stent, sleeve or coating (e.g., a polymer coating) to maintain patency of the secondary passageway 12.

In at least some applications, the coronary vein lumen CVL may be purposely blocked (e.g., ligated, embolized, fused, welded, clamped, etc.) at site(s) upstream and/or downstream of the transmyocardial passageway 10. As shown in Figure 1b, when the transmyocardial passageway 10 formed for the purpose of shunting oxygenated blood into the coronary vein lumen CVL, a proximal embolization member 14a may be positioned within the coronary vein lumen CVL, immediately upstream of transmyocardial passageway 10, to ensure that the shunted blood will flow, in the desired retrograde direction through the coronary vein CV. Similarly, as shown in Figure 1c, when a secondary bloodflow passageway 12 is formed to carry the oxygenated blood from the coronary vein lumen CVL into the coronary artery lumen CAL, downstream of the obstruction OB, a distal embolization member 14b may be positioned within the coronary vein lumen CVL immediately downstream of the secondary bloodflow passageway 12, to divert the flow of blood through the secondary bloodflow passageway 12.

Examples of methods for forming the optional secondary bloodflow passageway(s) 12 between the coronary vein CV and coronary artery CA are described in United States Provisional Specification Nos. 60/005,164, filed October 13, 1995 and 60/010,614 filed February 2, 1996, the entire disclosures of which are expressly incorporated herein by reference.

The proximal embolization member 14a and/or distal 14b embolization member may comprise any suitable type of lumen blocking matter or apparatus, examples of which are the embolization coils described in United States Patent Nos. 5,382,260 (Dormandy, Jr. et al.), 5,108,407 (Geremia et al.), and 5,256,146 (Ensminger, et al.). Alternatively, the coronary vein lumen CVL may be closed off at the sites of the proximal 14a and/or distal 14b

embolization members by any suitable alternative means, such as clamping, clipping, ligating, fusing, welding or adhesively conjoining the inner walls of the coronary vein lumen CVL so as to provide the desired blocking of bloodflow therethrough.

Figure 1d shows an alternative embodiment of the method of the present invention wherein a secondary bloodflow passageway 12 of the above-described type has been created between the coronary vein CV and coronary artery CA, and wherein the transmyocardial bloodflow passageway 10a extends from the chamber of the heart (e.g., left ventricle) such secondary bloodflow passageway 12.

II. <u>TMDCR Procedures Wherein Temporary A-V Fistula is Used to Facilitate Formation of Transmyocardial Passageway Entering Coronary Artery Downstream of Obstruction or Other Intraluminal Procedure</u>

Figures 11a-11b show an alternative TMDCR procedure of the present invention wherein a passageway-forming catheter 100 is initially advanced into a coronary vein CV which is situated adjacent a coronary artery CA in which an obstruction OB is present. When the distal end of the passageway-forming catheter 100 has been advanced to a location which is adjacent the segment of the coronary artery CA downstream of the obstruction OB, the passageway forming catheter 100 is oriented appropriately and a tissue-penetrating element 102 is passed out of the catheter 100, through the wall of the coronary vein, through any tissue located between the coronary vein CV and coronary artery CA, through the wall of the coronary artery CA and into the lumen of the coronary artery CA at a site downstream of the obstruction OB. In this manner, an arterio-venous passageway 104 is formed between the coronary vein CV and coronary artery CA.

After the distal end of the tissue-penetrating member 102 is advanced into the lumen of the coronary artery, a guidewire 104 is advanced through a lumen

formed in the tissue-penetrating element 102 such that the guidewire enters the lumen of the coronary artery CA. Thereafter, the tissue-penetrating element 102 may be retracted into the catheter 100, and the catheter 100 may be further advanced over the guidewire 104 such that the distal portion of the catheter will pass through the arterio-venous passageway 104 and into the lumen of the coronary artery. Thereafter, the guidewire 104 is once again retracted into the tissue-penetrating element 102 and the catheter 100 is rotationally reoriented, as necessary, to direct the tissue-penetrating element 102 toward the left ventricle LF. Thereafter, the tissue-penetrating element 102 is advanced from the catheter 100, through the wall of the coronary artery CA, through the myocardium M and into the left ventricle LV. This results in the formation of a transmyocardial passageway 10 in accordance with the present invention. If desired, the guidewire 104 may then be once again passed through the lumen of the tissue-penetrating element 102 and into the left ventricle LV such that the tissue-penetrating element 102 may be retracted into the catheter 102 while the guidewire 104 remains extended through the transmyocardial passageway 10 and into the left ventricle LV. In this manner, the guidewire 104 may be used to guide the advancement of one or more passageway-modifying devices, and/or the placement of an internal sleeve, stent, valve or other apparatus within the transmyocardial passageway 10 as known in the prior art, described herein, or described in applicant's earlier filed United States Patent Application Serial Nos. 08/730,327 and 08/730,496 and the corresponding counterparts thereof filed internationally under the PCT.

Thereafter, with the tissue-penetrating element 102 and guidewire 104 retracted into the catheter 100, the catheter 100 is extracted and removed from the body. The arterio-venous passageway 104 is then closed off (i.e., sealed, fused, cauterized, blocked, occluded, plugged, or

the coronary blood vessel CBV in the perfusive direction PD, as shown. Thereafter, during systolic relaxation of the heart, the relatively low filling pressure within the left ventricle LV will draw the occluder member 26 to its first (closed) position whereby the occluder member 26 will prevent blood from regurgitating or moving in the backflow direction BD from the lumen of the coronary blood vessel CBV , out of the side aperture 22, and into the bloodflow passageway 10. In this manner the first embodiment of the valving apparatus 20 serves to facilitate efficient pumping of oxygenated blood from the left ventricle and into the lumen of the coronary blood vessel CBV, to improve the flow of oxygenated blood to an ischemic or blood-flow-deprived region of the myocardium M.

As shown in Figure 2a, a closure member 21, in the nature of an end cap, may be formed on the upstream end of the apparatus 20 so as to completely or substantially block the flow of blood through the coronary blood vessel CBV and into the upstream end of the bore 24 of the apparatus 20. The optional inclusion of the end closure member 21 in the apparatus 20 may serve to obviate any need for the placement of a proximal embolization member 14a within the lumen of the coronary blood vessel CBV, upstream of the valving apparatus 20.

**b. Intravascular Valving Apparatus-Second Embodiment**

Figure 3 shows a second embodiment of the intravascular valving apparatus 30 which comprises a generally cylindrical body having an axial bore 34 extending longitudinally therethrough and a pair of occluder members 46 positioned therewithin, and a side aperture 32 formed in the cylindrical sidewall of the apparatus 30, behind the occluder members 36. Each occluder member 36 is affixed at least one point to the cylindrical body of the apparatus 30, and may comprise any suitable structure or openable and closeable passage,

such as a self-sealing slit or hole, or a hinged leaflet or pliable elastomeric member. The occluder members 46 are alternately moveable between first positions wherein the occluder members 36 directly contact one another so as to prevent blood from backflowing in the backflow direction BD through the axial bore 34 of the apparatus 30, and second positions wherein the occluder members 36 move out of contact with one another such that blood may flow through the axial bore 34 of the apparatus 30 in the perfusion direction PD. The side aperture 32 is preferably as large as or larger than the diameter of the bloodflow passageway 10 which extends through the myocardium M from the left ventricle LV to the lumen of the coronary blood vessel CBV. This embodiment of the apparatus 30 is implanted in the lumen of the coronary blood vessel CBV such that its side aperture 32 is directly aligned with the bloodflow passageway 10 so that blood may flow through the bloodflow passageway 10, into the axial bore 34 of the apparatus 30.

During systolic contraction of the heart the relatively high pressures created in the left ventricle LV will force blood to flow through the passageway 10 into the axial bore 34 of the valving apparatus 30. Such systolic bloodflow will move the occluder members 36 to their second (i.e., open) positions, thereby allowing the blood to flow through the lumen of the coronary blood vessel in the perfusion direction PD. Thereafter, when the heart undergoes diastolic relaxation, the relatively low filling pressures created within the left ventricle LV will draw the occluder members 36 to their first (ie. closed) positions, thereby preventing blood from regurgitating or backflowing out of the side aperture 32, in the backflow direction BD. In this manner, this second embodiment of the intravascular valving apparatus 30 serves to facilitate efficient pumping of oxygenated blood from the left ventricle LV and through the lumen of the coronary blood vessel CBV, in order to provide